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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/599,502	04/08/2008	Michele Coati	7202-124 (194359)	9945
30448	7590	03/07/2011	EXAMINER	
AKERMAN SENTERFITT P.O. BOX 3188 WEST PALM BEACH, FL 33402-3188			CUMBERLEDGE, JERRY	
ART UNIT		PAPER NUMBER		
3733				
NOTIFICATION DATE		DELIVERY MODE		
03/07/2011		ELECTRONIC		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

ip@akerman.com

Office Action Summary	Application No.	Applicant(s)	
	10/599,502	COATI ET AL.	
	Examiner	Art Unit	
	JERRY CUMBERLEDGE	3733	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 29 September 2006.

2a) This action is **FINAL**. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-37 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 1-37 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on 29 September 2006 is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some * c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413)
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail Date. _____ .
3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)	5) <input type="checkbox"/> Notice of Informal Patent Application
Paper No(s)/Mail Date <u>12/11/2006</u> .	6) <input type="checkbox"/> Other: _____ .

DETAILED ACTION

Drawings

The drawings are objected to because they are blurry and indistinct. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-37 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are replete with grammatical and idiomatic errors, and further include numerous antecedent basis problems. Examples include:

Claim 3 "...wherein it comprises..." It is unclear what "it" is.

Claim 19 "...wherein it comprises..." It is unclear what "it" is.

Claim 25 "... wherein each element is housed in a corresponding groove having the function of seat circumferentially developing along the side surface of the stem..." It is unclear whether this is the same "seat" referred to earlier or another "seat".

Claim 24 "...wherein the control screw is blacklash-like housed..." It is unclear what the term "blacklash" refers to.

Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-12, as best understood by the examiner, are rejected under 35 U.S.C. 102(e) as being anticipated by Biedermann et al. (US Pub. 2005/0187555 A1).

Biedermann et al. disclose an intramedullary nail suitable for insertion in a fractured elongate bone (Fig. 9a)(Fig. 9b) comprising a stem (Fig. 9a, ref. 60) extending between a proximal end (Fig. 9a, closer to ref. 2) and a distal end of the nail (Fig. 9a, closer to ref. 3) comprising a plurality of elements (Fig. 9a, ref. 70) realized with at least a shape-memory material (paragraph 0052), a plurality of seats formed in the stem for housing said elements (Fig. 9a, ref. 80) and in that said elements are suitable to take a first shape wherein they are retractably housed in the respective seats (Fig. 9a) and a second shape wherein they project from the respective seats (Fig. 9b) that wherein the stem comprises at least two half-cylinders united along the length (Fig. 9a, i.e. two half cylinders joined yield one full cylinder as shown). The seats of the stem are made of a plurality of transversal slots (Fig. 9a, ref. 80) or elongate holes which extend passing from one side of the stem to the other (Fig. 9a). It comprises inserts structurally independent from the stem and comprising at least one of said shape-memory elements (Fig. 9a, ref. 70), each of said inserts being suitable for insertion in a corresponding seat (Fig. 9a). Each of said inserts comprises two shape-memory elements (Fig. 9a, attached and free ends of refs. 70) which are connected by means of a central connection element (Fig. 9a, intermediate portion of ref. 70). Each insert has a substantially fork-like shape (Fig. 9a). Each fork-like insert is suitable to be housed in a corresponding transversal slot so that the two elements are arranged on sides opposite to the stem (Fig. 9a). The inserts are flanked in succession along the length of the stem

(Fig. 9a). The inserts are distributed on the side surface of the stem in correspondence with the proximal end and the distal end (Fig. 9a, as they are found along the length and around the periphery of the device). The inserts are offset with respect to each other of 90° sexagesimal (Fig. 9a, as they are found along the length and around the periphery of the device). The two elements of each insert comprise two opposite tabs having a flexural memory (Fig. 9a, attached and free ends of refs. 70) (paragraph 0052). The tabs on the surface facing outwards the stem have a substantially sawtooth-like profile (paragraph 0048).

Regarding claim 4, (“...each insert is inserted by pressure in the respective seat...”), the examiner notes that this claim is being treated as a product-by-process claim. It is noted that the device of appears to be substantially identical to the device claimed, although possibly produced by a different process, therefore the burden is upon the applicant to come forward with evidence establishing an unobvious difference between the two. *In re Marosi*, 218 USPQ 289 (Fed. Cir. 1983).

Regarding claim 12, (“...the inserts are of the multilaminar type, i.e. it is realised by means of a plurality of overlapped foils of shape-memory material...”), the examiner notes that this claim is being treated as a product-by-process claim. It is noted that the device of appears to be substantially identical to the device claimed, although possibly produced by a different process (*i.e.* the inserts are possibly produced from a single sheet or layer of material), therefore the burden is upon the applicant to come forward with evidence establishing an unobvious difference between the two. *In re Marosi*, 218 USPQ 289 (Fed. Cir. 1983).

With regard to statements of intended use and other functional statements, they do not impose any structural limitations on the claims distinguishable over the device of Biedermann et al., which is capable of being used as claimed if one so desires to do so.

In re Casey, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). Furthermore, the law of anticipation does not require that the reference “teach” what the subject patent teaches, but rather it is only necessary that the claims under attack “read on” something in the reference. *Kalman v. Kimberly Clark Corp.*, 218 USPQ 781 (CCPA 1983). Furthermore, the manner in which a device is intended to be employed does not differentiate the claimed apparatus from prior art apparatus satisfying the claimed structural limitations. *Ex parte Masham*, 2 USPQ2d 1647 (1987).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 3, 5, 11 and 13-37, as best understood by the examiner, are rejected under 35 U.S.C. 103(a) as being unpatentable over Bramlet et al. (US Pat. 6,488,684 B2) in view of Biedermann et al. (US Pub. 2005/0187555 A1).

Bramlet et al. disclose intramedullary nail (Fig. 4B, remarked, below) suitable for insertion in a fractured elongate bone comprising a stem extending between a proximal

end and a distal end of the nail comprising a plurality of elements, a plurality of seats formed in the stem for housing said elements and in that said elements are suitable to take a first shape wherein they are retractably housed in the respective seats and a second shape wherein they project from the respective seats that wherein the stem comprises at least two half-cylinders united along the length (Fig. 4B). It comprises inserts structurally independent from the stem and comprising at least one of said shape-memory elements, each of said inserts being suitable for insertion in a corresponding seat (Fig. 4B). Each of said inserts comprises two shape-memory elements which are connected by means of a central connection element (Fig. 4B, remarked, left and right elements connected by refs. 2). The two elements of each insert comprise two opposite tabs (Fig. 4B, left and right elements). The two elements of the insert are connected by means of a cylindrical sleeve (Fig. 4B, refs. 2). On the cylindrical sleeve two opposite grooves are provided (Fig. 4B, openings through which elements protrude)(Fig. 3B), being offset substantially of a right angle with respect to said two elements (Fig. 4B) and suitable to house at least partially the elements of a flanked cylindrical sleeve (Fig. 3B, when the elements are protruding). Each element is housed in a corresponding groove having the function of seat axially developing along the side surface of the stem (Fig. 4B, remarked, below, seats comprise grooves). Each element is fixed to a first end of the stem (Fig. 4B, end of elements which are directly attached to stem) and it has a second free end suitable to be arranged, in correspondence with said second shape, outside the stem (Fig. 3B, free ends which may move to outside of stem). The groove has a U-shaped profile (Fig. 4B). Each of

said seats is made of a narrow section made at the two ends of the stem (Fig. 4B) and in that said narrow section is suitable to retractably house a cylindrical sleeve of shape-memory material (Fig. 4B). The narrow section has a thread at the stem free (Fig. 4B, threaded section of stem), a retaining ring of the cylindrical sleeve being screwed on said thread (Fig. 4B, retaining ring surrounding threaded portion of stem, formed by adjacent element of stem). The narrow section has a thread at the stem free, a retaining plug of the cylindrical sleeve being screwed on said thread (Fig. 4B, retaining ring surrounding threaded portion of stem, formed by adjacent element of stem). The stem is a cylindrical tube (Fig. 4B) and in that said elements realized with a shape-memory material are two inserts (e.g. refs. 2 Fig. 4B), one of them placed at the proximal end and the other at the distal end of the nail said inserts being housed in correspondence with respective portions with lowered section of the stem forming said housing seats (Fig. 4B). Each insert is shaped as a cylindrical sleeve (Fig. 4B, refs. 2) which comprises a plurality of longitudinal cuts (Fig. 4B, formed between the "elements") the cuts cutting the thickness of the cylindrical sleeve of the insert (Fig. 4B) and defining a plurality of tongues (Fig. 4B, remarked below, "elements") suitable to project with respect to the respective seat (Fig. 3B). Regarding claims 30-33, the examiner notes that claim 29 recites the cylindrical sleeve functionally, but does not positively recite the sleeve as part of the structure of the device (i.e. "...is suitable to retractably house a cylindrical sleeve of shape-memory material...") and therefore the claimed invention must only be capable of housing a cylindrical sleeve.

Bramlet et al. disclose an intramedullary nail (Fig. 4B, remarked, below) suitable for insertion in a fractured elongate bone comprising a stem extending between a proximal end and a distal end, a plurality of elements, and a plurality of seats formed in the stem for housing said elements, wherein said elements are suitable to take a first shape wherein they are retractably housed in the respective seats and a second shape wherein they project from the respective seats, wherein the nail includes inserts, structurally independent from the stem and comprising at least one of said elements (Fig. 4B, inserts comprise elements), each of said inserts being suitable for insertion in a corresponding seat, wherein each insert includes a plurality of overlapped foils (e.g. elements overlap each other, as they are found around circumference of device). Each insert has substantially fork-like shaped. For ensuring a stable assembly of the metallic foils, the insert is provided with a pair of blocking pins (e.g. Fig. 6B, ref. 15) inserted transversally to the metallic foils (Fig. 6B).

Bramlet et al. disclose an intramedullary nail (Fig. 4B, remarked, below) suitable for insertion in a fractured elongate bone comprising a stem extending between a proximal end and a distal end, a plurality of elements, and a plurality of seats formed in the stem for housing said elements, wherein said elements are suitable to take a first shape wherein they are retractably housed in the respective seats and a second shape wherein they project from the respective seats, wherein it comprises a tubular jacket having a side wall which sheathes the stem and has the function of retaining the shape-memory elements in the first shape, i.e in the close retractable position in the seats when the nail is inserted in the bone. The jacket comprises a plurality of transversal

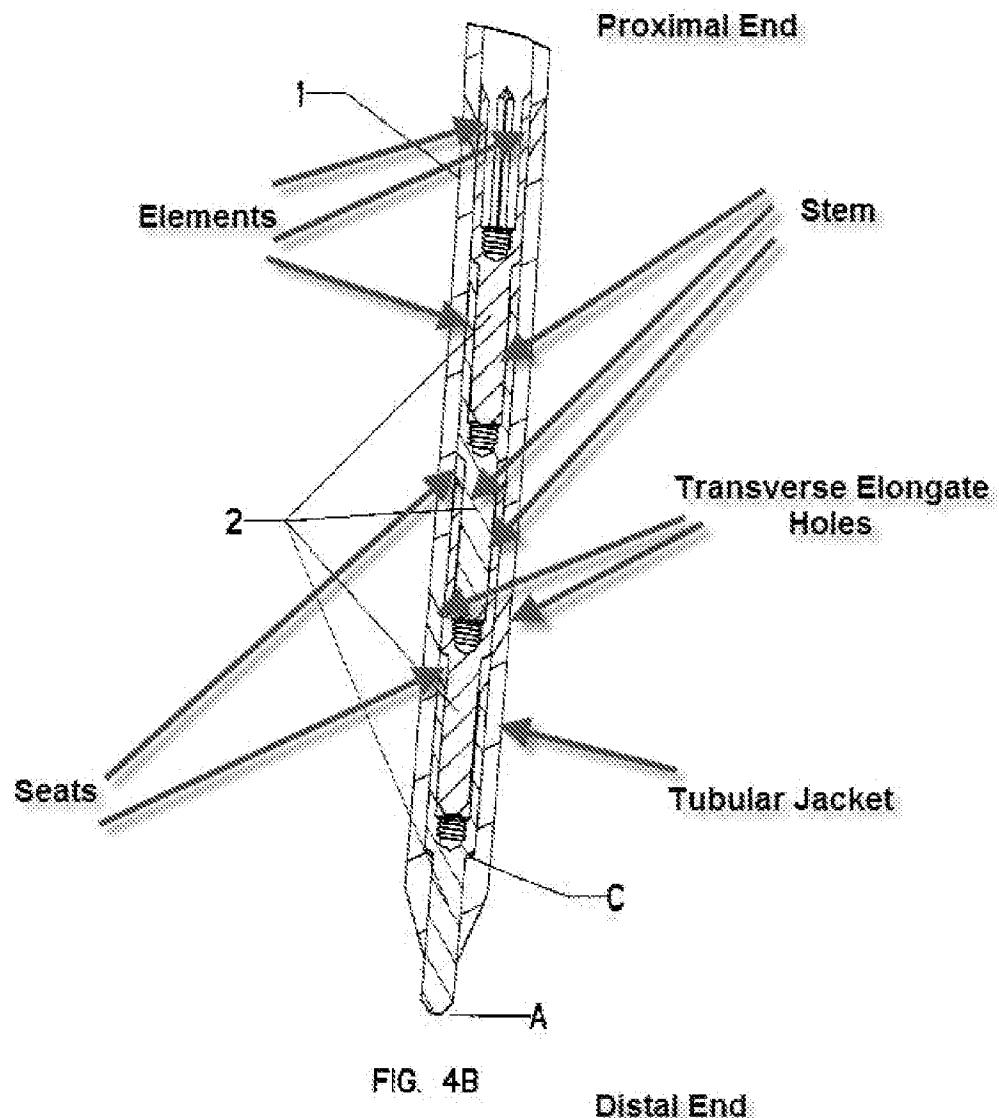
elongate holes made on the tubular wall (Fig., 4B, remarked, below). The jacket and the stem can be shifted with respect to each other from a first operative position during which the side wall of the jacket retains the shape-memory elements in the first retractable shape in the seats (Fig. 4B), and a second operative position wherein the transversal holes of the jacket are aligned in the seats of the stem, so as to allow the arrangement of the elements projecting from the respective seats (Fig. 3B). The shift relative to the jacket with respect to the stem occurs along the axis of the nail (Fig. 4B)(Fig. 3B). It comprises a control screw suitable to be rigidly connected to a head portion of the stem for controlling, by means of rotation around its own axis, the axial shift of the stem with respect to the jacket (column 5, lines 53-67)(column 6, lines 1-40) . It comprises an internally hollow tube (Fig. 7b, ref. 22) suitable to be rigidly connected to a head portion of the jacket (Fig. 3B) and wherein the control screw is housed (Fig. 3B). Each element is housed in a corresponding groove having the function of a seat (Fig. 4B, remarked, below, seats comprise grooves) circumferentially developing along the side surface of the stem (Fig. 4B).

Bramlet et al. disclose the claimed invention except for the elements comprising a shape-memory material.

Biedermann et al. disclose an intramedullary nail suitable for insertion in a fractured elongate bone (Fig. 9a)(Fig. 9b) comprising a stem (Fig. 9a, ref. 60) extending between a proximal end (Fig. 9a, closer to ref. 2) and a distal end of the nail (Fig. 9a, closer to ref. 3) comprising a plurality of elements (Fig. 9a, ref. 70) realized with at least a shape-memory material (paragraph 0052), a plurality of seats formed in the stem for

housing said elements (Fig. 9a, ref. 80) and in that said elements are suitable to take a first shape wherein they are retractably housed in the respective seats (Fig. 9a) and a second shape wherein they project from the respective seats (Fig. 9b). The higher elasticity of the shape-memory barb elements simplifies the handling and provides additional security in anchoring the bone anchoring element in the bone (paragraph 0052).

It would have been obvious to a person having ordinary skill in the art to have constructed to have constructed the elements of Bramlet et al. from a shape-memory material as taught by Biedermann et al., in order to simplify the handling and provide additional security in anchoring the bone anchoring element in the bone (paragraph 0052).



Regarding claims 36 and 37, Bramlet et al. in view of Biedermann et al. disclose the claimed invention except for the narrow section has an outer prismatic shape corresponding to an inner conjugated prismatic shape of the central hole of the cylindrical sleeve; and the outer prismatic shape of said narrow section and of said central hole of the cylindrical sleeve is a regular octagonal prism. It would have been an obvious matter of design choice to one skilled in the art at the time the invention was made to have constructed the narrow section with an outer prismatic shape corresponding to an inner conjugated prismatic shape of the central hole of the cylindrical sleeve; and the outer prismatic shape of said narrow section and of said central hole of the cylindrical sleeve being a regular octagonal prism, since applicant has not disclosed that such solve any stated problem. *In re Dailey and Eilers*, 149 USPQ 47 (1966).

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Please see attached PTO-892.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JERRY CUMBERLEDGE whose telephone number is (571)272-1346. The examiner can normally be reached on Monday-Friday 9:00-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on (571)272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/J. C./
Examiner, Art Unit 3733
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